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PATENT TRADEMARK OFFICE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re: Patent Application for Stelpflug **Dated:** Oct 4, 2002
Serial 09/811,050 **Art Unit:** 1638
No.:
Filed: March 15, 2001 **Examiner:** Medina Ibrahim
For: Inbred Corn Line G3001 **Action:** Amendment

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To: The Commissioner of Patents and Trademarks, Washington, DC 20231

The Examiner objected to the Statement of deposit in the specification, because it does not include the deposit accession number. Additionally, the Examiner objected to claims 1, 6, 9 for failing to recite complete deposit Accession Information. The applicant respectfully requests that the Examiner withhold these objections until there are allowable claims in this case. The deposit accession number will be provided later in the prosecution if the issue fee is to be paid.

The Examiner indicated that Claims were rejected under 35 USC § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to use the invention. The Examiner states that the specification does not disclose a reproducible method to obtain the exact same seed. The applicant again requests that the Examiner withhold the objection to claims 1-18 based in paragraph one of the Examiner's office action until such time as there is an indication that claims are allowable in this matter. The applicant bases this on the belief that deposit of the biological material will eliminate the Examiner's objection.

In Paragraph 2, claim 18 was rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to use the invention. The Examiner alleged that the method for identifying the inbred corn seed G3001 does not disclose a repeatable

process to reproduce the claimed seed. Therefore, the person skilled in the art would not be able to practice the claimed invention without undue experimentation.

The applicant believes that this rejection of claim 18 will be removed upon deposit of the seed in this matter and therefore requests that this matter be withheld until such time as the Examiner indicates allowable claims as the solution to this rejection of claim 18 clearly lies in deposit of the material in the ATCC. There is clearly no undue experimentation for a person of ordinary skill in the art to determine if the reproduced seed is the same as the claimed seed with a representative sample or deposit.

At the bottom of page 4, the Examiner made claim rejections under 35 U.S.C. §112 second paragraph, to claims 1-5, 7-18, as being indefinite for failing to particularly point out and distinctly claiming the subject matter which the applicant regards as the invention. The Examiner indicated that, in claim 1, "said" should be inserted prior to "seed", to show proper dependency and claims 2-5, 7-8, 10, and 12-18 were included in the rejection. Using "said" in this case would make the claim unclear as the seed being claimed are not limited to the deposited seed as "said" may suggest, but to the seed of the type that has been deposited. Thus to further clarify this issue the applicant has amended claim one, six and nine to state that representative seed of the line has been deposited in the ATCC under the accession No.

The Examiner is stating that claim 2 needs the term, "growing" for clarification. The Applicant respectfully disagrees that this claim is unclear. "Produced" is sufficient for clarification. The applicant has indicated that corn plants can be produced at least by culturing techniques and by growing techniques. Thus the use of growing is a limitation that is not needed for clarification and the ordinarily skilled person in the art would be aware of how a seed can produce a corn plant.

The Examiner's suggestion will be complied with by the amendment of claim three and four to depend from claim 2. Claim 3 has been amended to reflect that a tissue culture

of regenerable cells of G3001 is a novel composition of matter like the seed of G3001. Additionally, claim 5 has been clarified by adding **"the inbred line designated"**.

The Examiner has indicated that claim 7 would be clarified by being followed by a method step. The Applicant has introduced not one but two method steps: the formation of across of the maize plants and the harvesting of the seed.

The applicant has amended claim 8 to give the correct antecedent basis in light of the amendment of claim 7.

The applicant has amended claim 9 to indicate that one plant is nonpollen producing and is the seed producing plant.

Claims 12, 13, 15, and 16 have been amended to reflect the Examiner's suggested changes and to introduce some additional clarity that was not suggested by the Examiner but was thought to be appropriate by the Applicant. Claims 14 and 17 have been amended to clarify that one of the lines carries the mutant gene or the transgene.

In claims 15-16 the Examiner has asked if the mutant gene is an endogenous gene or a transgene. The applicant does not know that this makes a difference. Both type of genes mutations and mutant transgene are well known in the art and are adequately described in the application. However the claim has been amended to provide clarity as it is intended to cover a gene with a mutation regardless of how that mutation was originally placed in the genome of G3001.

Claim 18 has been amended to clarify the language and to provide a final step that more closely correlates with the method step in the preamble of the claim.

Claim 19 has been newly added and it claims the use of biotechnology techniques for identifying the seed.

Claim 20 has been newly added and it claims the pollen of the plants of claim 2. The newly added claims are dependent claims and are not believed to incur any additional claim fees. If the is incorrect and claims fees are required then the Applicant requests that the Examiner immediately notify the applicant so that deposit account information can be provided.

Written Description

The Examiner has rejected under 35 USC§ 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), had possession of the claimed invention. The claimed invention allegedly lacks written description under current written description guidelines.

The claims are drawn to hybrid corn seeds/plants or F1 generation plants produced from crossing two inbred parent corn plants, wherein the identity of only one of the inbred parent plant is know, the other is unknown.

The PTO in its response to the comments concerning the new guidelines on written description noted, " Eli Lilly identified a set of circumstances in which the words of the claim did not, without more, adequately convey to others that applicants had possession of what they claimed. When the name of a novel chemical compound does not convey sufficient structural information about the compound to identify the compound, merely reciting the name is not enough to show that the inventor had possession of the compound at the time the name was written."

This is not the case here. The biological material that is G3001 is to be deposited. The ordinarily skilled person in the art knows how to identify the basic genetic footprint of G3001 in a pedigree plant.

Additionally there is a **presumption that the requirement is c mplied with**. The Guidelines indicate that there is a '**strong presumption**' that an adequate written

description of the claimed invention is present when the application is filed, consistent with In re Wertheim, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976) ('we are of the opinion that the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims.').

The PTO supports that in most cases, the statement that '**an originally filed claim is its own written description**,' is borne out because the claim language conveys to others of skill in the art that the applicant was '**in possession**' of what is claimed. In this case the originally filed claim is its own written description and the specification itself shows abundant evidence that the applicant was in possession of the invention. Table 4 shows the line G3001 in 26 different hybrid combinations. If you presume that there was only one hybrid plant in each of these trials (there of course were many, many more hybrid plants and repetitions) and that each of these individual 26 hybrids produced only one cob. And if you further assume that each of those cobs only produced 500 kernels then Table four indicates that at the time of the invention the applicant possessed at least 3500 hybrid seeds according to the claims and at least 3500 seeds having an ancestor of G3001.

In actually fact the minimum estimated number of seeds having an ancestor of G3001 that were produced by those 26 different repetitions of plots of hybrids in the two seasons there were 30,873,926 seeds which were hybrid seed each having an ancestor of G3001. This 30 million number, of course, does not include the number of seeds that were produced in hybrid crosses with only one year of data nor does this number include the seeds produced in the yield plots that are shown in the later tables in the specification.

It is clear that the Applicant was in possession of 30 million examples of the invention as claimed. Additionally, there would be no hybrid seed or plants with the ancestor of G3001 but for the invention of G3001. The ordinarily skilled person in the art recognizes that having seed of the hybrid with a parent being G3001 would place the

inventors in possession of the invention when the application was on file. The use of G3001 as an ancestor is also within the parameters of what is expected by the ordinarily skilled person in the art. The ordinarily skilled person in the art of plant breeding records the pedigree of lines. This pedigree is painstakingly listed and maintained for breeding and selection purposes. So if a line had an ancestor of G3001, in standard industry practice, any party breeding with the G3001 material would document the resultant progeny as a descendent having G3001 as an ancestor.

Second, the ordinarily skilled person in the art is well aware that without any undue experimentation that the genetic fingerprint of the deposited material can be determined. This genetic fingerprint can be tracked to identify portions of the G3001 genetic fingerprint in the hybrid combination and/or in the descendents the which have G3001 as an ancestor or having G3001 as a parent in a hybrid seed in their pedigrees. Additionally, the use of markers also allows for identification of plant material that does not have G3001 as an ancestor.

Although, this publication does not concern the same organisms (humans instead of maize) markers such as RFLP have also been employed to determine the genetic fingerprint of humans when doing parentage testing for paternity. The identity of children that have been kidnapped or adopted during the human rights violations that occurred in Argentina in the eighties has been addressed by employing the test to generate the genetic fingerprint in combination with other genetic detection using maternally inherited mitochondrial sequences. (See The Science of Genetics, published by ISU (1999) "Current Investigations: How Can Genetics Be Used to Solve A Human Rights Crime?" Pg. 93 of Chapter 4.) Similarly, markers are employed in maize lines to establish fingerprinted using these biotechnology techniques to determine the lines likely parentage.

In fact, these biotechnology techniques are so well accepted by the ordinarily skilled person in the art of plant breeding that governmental authorities in Europe are debating whether to use these biotechnology marker techniques to determine the distinctness,

stability and uniformity of plants submitted for variety protection and/or national registration.

In addition to detection of parentage by markers and pedigrees it is a standard breeding procedure to look at subsequent generations of plants for phenotypical traits which are well known to be highly inheritable. Breeding procedures to detect these phenotypical traits include doing grow outs of the plants and the ancestors in side by side tests in a field to detect the trait similarities of the lines with similar genetic pedigrees. In fact a combination of these types of pedigree tracking and identification has been in use for years in the seed industry, and was a centerpiece of a germplasm misappropriation litigation in the early 1990s between Pioneer and Holden's concerning the questionable pedigree of Holden's LH 38 material.

Concerning the written description requirements set forth in the guidelines, it is clear that G3001 and claims 6-17 are in full compliance.

The guidelines state that,

"...The written description requirement, a question of fact, ensures that the inventor conveys to others that he or she had possession of the claimed invention; whereas, the enablement requirement, a question of law, ensures that the inventor conveys to others how to make and use the claimed invention."... "to satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Possession may be shown in a variety of ways including description of an actual reduction to practice"

The Applicant has satisfied the written description requirement. The specification shows actual reduction to practice and it is well understood and explained in the written description the various ways which new corn plants and seeds can form either hybrid seed or plants having G3001 as an ancestor. The specification data inescapably leads to the conclusion that the inventors were in possession of numerous examples, at least 30 million examples, of the claimed invention at the time of filing. Additionally, the methods for tracking pedigrees and thus ancestors is undeniably deeply ingrained in the breeding process of plant breeders that are skilled in the art. Methods for detecting the genetic carry over were well known in the art as of filing and was publicly available process, as shown in Quantitative Genetics in Maize Breeding, 2nd Ed., Chapter 5, page 116, Hallauer and Miranda, ISU Press/Ames (1988) that shows that a number of maize traits are very inheritable (see page 118). This general inheritability of traits and the ability to employing markers to detect the genetic movement of the material of the invention through the descendent lines has been in use by the ordinarily skilled person in the art since at least the late eighties.

Methods for tracking pedigrees and thus ancestors determining the carry over into these descendents, of the genetic traits and characteristics of an ancestor through marker assisted breeding is also well known by those of skill in the art. The book entitled Genetics and Analysis of Quantitative Traits published by Sinauer Associates, Inc. and written by M. Lynch and B Walsh, pages 390-393 of Chapter 14 (1998), lists a number of molecular markers and the genetic material that these markers are detecting. These marker techniques are well known and are used in the maize industry. These biological techniques can be employed by the person of ordinary skill in the art to measure DNA variation in plants. The oldest method was allozymes, which is being replaced by one of the simplest marker approaches, which is a method that uses RFLP's. Numerous other marker approaches are which are in standard use in the maize industry are also listed in this publication.

The guidelines clearly state that for the written description the, "Possession may be shown in a variety of ways including description of an actual reduction to practice" In the present application the actual reduction to practice is shown 30 million times.

CLAIMS REJECTIONS- 35 USC §102/103

The applicant believes that the Examiner rejection is inappropriate. The claimed invention in claims 6-17 require that G3001 be in the pedigree of the descendents and the invention underlying U.S. 5,866,763 does not suggest lines that have G3001 as an ancestor. In fact the line underlying U.S. 5,899,763 teaches the production of descendents from that line and not breeding with G3001. Clearly, ZS01220 differs from G3001 and its descendents in that it has no G3001. ZS01220 teaches breeding with ZS01220, which has very different electrophoresis results on the genetic side of the equation compared to G3001. Additionally in hybrid combination the two inbreds evidence very different days to maturity. ZS01220 has an RM of 121 days, compared to G3001 which shows an RM of only 107 days in hybrid combination. The glume ring color of ZS01220 is white but the glume ring color of G3001 is red. Additionally ZS01220 has a yellow/green brace root color compared with the G3001 line which has a red brace root color. ZS01220 has a "leafy" shoots at flowering in contrast G3001 only has "bald" shoots at flowering. The two lines at flowering evidence different silk colors red for G3001 verses pale green. The two lines are both maize inbreds but other than that similarity the two lines are very different from each other and thus ZS01220 should not be novelty destroying nor should ZS01220 be the basis for an obviousness rejection. However, even if these two inbreds were more similar claims 6-17 still would not suggest nor taught by the patent on ZS01220. The claims 6-17 claim lines G3001 in hybrid combination and as an ancestor. ZS01220 teaches breeding with an entirely different composition of matter, an inbred with very different traits. Additionally there is no likelihood that someone breeding with ZS01220 would achieve the invention claimed in claims 6-17 as these claims all require the use of G3001. The patent to ZS01220 does not teach nor suggest G3001 as a breeding tool. Thus the Examiner is respectfully requested to reconsider this rejection and if deemed appropriate to please remove this rejection to the listed claims under 102/103.



Respectfully submitted,

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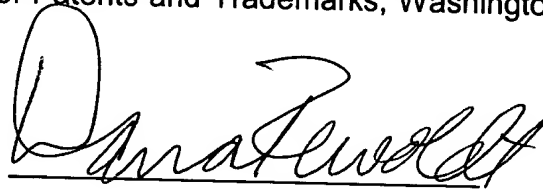
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CERTIFICATE OF MAILING UNDER 37 C.F.R. 1.8

I hereby certify that the foregoing 17 page Amendment with three attached references and both an unmarked and marked set of claims and postcard are being mailed to the Assistant Commissioner of Patents and Trademarks, Washington, DC 20231, on Oct 4, 2002.



S/N: 09/811,050

Our Reference No. G3001